

REMARKS

In claim 11 it has been specified that the granules are spherical, as indicated in claim 2 as initially filed, and in the specification page 5 line 1.

It has also been specified that starch is under granular form as it results from the whole description, in particular, page 3 line 3, page 4 line 2, page 5 line 20.

Support for claim 21 can be found in the specification at page 8, lines 3-5.

Claims have been drafted to overcome any objections under 35USC§112.

Claim 15 was considered by the Examiner as indefinite since it recites "consisting of" language while it refers to a Test B which requires granules that also have magnesium stearate.

Applicants respectfully disagree.

In fact, as explained during the interview, test B, which is described at page 6 lines 9-34, allows the evaluation of the tableting capacity of the spherical granules according to the invention.

For carrying out said test B, it is necessary to prepare tablets. Said tablets are prepared using the spherical granules according to the invention which consist in lactose and granular starch, and using a lubricant.

The lubricant is used as an auxiliary agent for the tableting and is not part of the invention.

The objection should thus be cancelled.

Claims 11-22 are rejected under 35USC§103 as being unpatentable over Saito et al. (US5,618,562).

Applicant respectfully disagrees.

As explained during the Interview, Saito et al. relates in fact to a medicinal granule which comprises an internal nucleus based on lactose, on which is applied an ascorbic acid matrix layer consisting of ascorbic acid, lactose and starch, said matrix layer being secured to the nucleus by a film layer based on shellac and ethyl cellulose in ethanol. Thus Saito et al. discloses a granule coated with a drug layer.

The granule according to the invention is a granule consisting of co-spray-dried lactose and granular starch, i.e. a homogeneous granule of a mixture of lactose and granular starch with no other component.

Thus, the granules according to the invention can in no way be deduced from Saito et al..

In view of the above, it is considered that the application is now in proper form for allowance.

Favorable consideration and prompt allowance of these claims are respectfully requested.

Respectfully submitted,

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